**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| UNITED STATES OF AMERICA | : | Hon. Cathy L. Waldor |
| | : | |
| v. | : | Mag. No. 21-9519 |
| | : | |
| ALAIN BOUAZIZ | : | **CRIMINAL COMPLAINT** |

I, Jean Kanokogi, the undersigned complainant being duly sworn, state the following is true and correct to the best of my knowledge and belief:

**SEE ATTACHMENT A**

I further state that I am a Special Agent with the Food and Drug Administration – Office of Criminal Investigations, and that this complaint is based on the following facts:

**SEE ATTACHMENT B**

by phone

Special Agent Jean Kanokogi
FDA-OCI

Sworn to before me by telephone pursuant
to F.R.C.P. 4.1(B)(2)(A), on November 23, 2021

HONORABLE CATHY L. WALDOR
UNITED STATES MAGISTRATE JUDGE

Signature of Judicial Officer

**ATTACHMENT A**
**(False Statements)**

From in or about February 2018 through on or about November 23, 2021, in the District of New Jersey and elsewhere, defendant

**ALAIN BOUAZIZ,**

did willfully and knowingly make materially false, fictitious, and fraudulent statements and representations in a matter within the jurisdiction of the executive branch of the Government of the United States, by submitting and causing to be submitted to the United States Food and Drug Administration false statements and forged documents in an attempt to gain control of Sanorex, a weight-loss pharmaceutical owned by a Pharmaceutical Company-1.

In violation of Title 18, United States Code, Section 1001(a)(2) and Section 2.

**ATTACHMENT B**

I, Jean Kanokogi, a Special Agent with the U.S. Food and Drug Administration – Office of Criminal Investigations, having conducted an investigation and having spoken with other individuals, have knowledge of the following facts. Because this Complaint is being submitted for the limited purpose of establishing probable cause, I have not included each and every fact known to me concerning this investigation. I have set forth only the facts that I believe are necessary to establish probable cause. All included statements are related in substance and in part. All dates and times are approximations.

1. At all times relevant to this Complaint, unless otherwise indicated:

a. Defendant ALAIN BOUAZIZ was a French citizen and resident of the United Arab Emirates. BOUAZIZ represented himself to be the Chief Operating Officer (COO) of Hexim Pharmaceuticals (Hexim), a company headquartered in Secaucus, New Jersey. Hexim was known as Alkopharma USA, Inc. until its name was changed in or about June 2013.

b. The United States Food and Drug Administration (FDA) was an agency of the United States charged with, among other things, protecting the public health by ensuring the safety, efficacy, and security of drugs sold in the United States. As part of the FDA's duties, it reviewed New Drug Applications (NDAs), through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. The FDA published the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, which listed the owner of each NDA. Under 21 C.F.R. § 314.72, an NDA may be transferred to a new owner. Applicants submitted an FDA Form-356h, application to market a new or abbreviated new drug or biologic for human use, to the FDA in order to, among other things, change the ownership of an NDA.

c. Sanorex (Mazindol) was a weight-loss pharmaceutical owned by a major international pharmaceutical company ("Pharmaceutical Company-1"). In or about 2008, Pharmaceutical Company-1 requested withdrawal of its Sanorex NDA from the FDA. Notice of this withdrawal application was published in the Federal Register in June 2009, meaning Sanorex could no longer be marketed in the United States.

d. In or about October 2009, Alkopharma purchased from Pharmaceutical Company-1 the rights to distribute a different pharmaceutical product in Europe. BOUAZIZ was listed in public records at the time as the president and CEO of Alkopharma. At no time did Hexim or BOUAZIZ obtain the rights to sell Sanorex or become the legal owner of the Sanorex NDA.

2. The FDA investigation shows that BOUAZIZ submitted forged documents and made false statements to the FDA, all in an effort to fraudulently gain control Sanorex and the right to sell it in the United States. BOUAZIZ's criminal scheme is described in the following paragraphs.

3. On or about February 13, 2018, BOUAZIZ caused a letter to be sent to the FDA that falsely stated that Hexim had purchased the North American rights to Sanorex and also requested a meeting with the FDA to discuss submission of a new marketing application for Sanorex. As BOUAZIZ knew, these representations were false because Hexim had not purchased the rights to Sanorex from Pharmaceutical Company-1. The FDA denied this initial meeting request for being substantially incomplete. On or about April 30, 2018, BOUAZIZ, caused another letter to be sent to the FDA, again requesting a meeting about Sanorex in an attempt to seek control of its NDA.

4. On or about May 1, 2018, BOUAZIZ, using his Hexim email address, sent an email to an FDA manager (the May 1 Email). In the signature block of the May 1 Email, BOUAZIZ described himself as Hexim's "C.O.O." and provided Hexim's physical address in Secaucus, New Jersey. The May 1 Email attached six documents as part of BOUAZIZ's fraudulent efforts to transfer ownership of Sanorex to Hexim.

5. Among the documents that BOUAZIZ attached to the May 1 Email was a cover letter that BOUAZIZ signed, purporting to request a meeting with the FDA in order to transfer Sanorex's NDA from Pharmaceutical Company-1 to Hexim. In addition, BOUAZIZ attached documents that purported to be: (1) an asset purchase agreement, dated October 30, 2009, between Pharmaceutical Company-1 and Alkopharma (the "Sanorex Asset Purchase Agreement") for a purchase price of $2 million; (2) an "Application for Change of Ownership of a Marketing Authorisation [sic]," dated October 31, 2014, signed by Pharmaceutical Company-1 (the "Sanorex Ownership Change Application"); (3) a completed FDA Form-356h signed by BOUAZIZ on behalf of Hexim (the "Form-356h"); (4) Pharmaceutical Company-l's Clinical Expert Statement for Sanorex; and (5) documents purporting to show that, in or about June 2013, Alkopharma changed its name to Hexim. None of these documents were part of a bona fide transaction between Hexim and Pharmaceutical Company-1. Instead, as BOUAZIZ knew, they were part of his efforts to fraudulently induce the FDA to switch control of Sanorex to BOUAZIZ's entity.

6. BOUAZIZ further caused a paper copy of these May 1 Email and attachments to be sent to the FDA, under the same cover letter described above. These paper documents were received by the FDA on or about May 11, 2018 and bore the address of Hexim's corporate headquarters in Secaucus, New Jersey.

7. The Form-356h indicated that Hexim was applying to market Sanorex. The Form-356h further indicated that the reason for the submission was "CHANGE

OD [SIC] OWNERSHIP OF SANOREX." The completed Form-356h that BOUAZIZ caused to be sent to the FDA bore an electronic signature, dated March 8, 2018, reflecting BOUAZIZ's email address. The Form-356h provided a warning that a willfully false statement is a criminal offense under 18 U.S.C. § 1001. I know from my training and experience that the ownership of an NDA is a material fact that is capable of influencing the FDA in approving or denying a Form 356h.

8. On or about July 30, 2018, the FDA wrote to BOUAZIZ acknowledging BOUAZIZ's correspondence and stating that the NDA for Sanorex had been transferred from Pharmaceutical Company-1 to Hexim. The letter nevertheless advised BOUAZIZ that Sanorex's NDA had previously been withdrawn by Pharmaceutical Company-1 and therefore he could "not market the product under this application and we will not accept supplements to this application. If you wish to pursue marketing of this product again, contact this division to discuss your options."

9. Subsequently, Pharmaceutical Company-1 learned that Sanorex's listing in the Orange Book had been changed without its knowledge or permission. Pharmaceutical Company-1 then contacted the FDA.

10. A review of the documents BOUAZIZ submitted to the FDA in or around May 2018 showed that they contained multiple forgeries. For example, the Sanorex Ownership Change Application that BOUAZIZ sent was dated October 31, 2014. But the individual who purportedly signed this document on behalf of Pharmaceutical Company-1 had ceased to be employed by Pharmaceutical Company-1 in or about January 2013, more than a year before the document BOUAZIZ submitted was supposedly signed.

11. In addition, the Sanorex Asset Purchase Agreement BOUAZIZ sent to the FDA appears to have been forged. Specifically, this document is an altered version of the actual agreement between Pharmaceutical Company-1 and Alkopharma to sell a different product, which was in fact dated October 30, 2009. Indeed, the preamble of the document BOUAZIZ submitted to the FDA is dated October 30, 2009, but the signature page he submitted is dated October 30, 2012. Furthermore, the individual who had supposedly signed the Sanorex Asset Purchase Agreement on behalf of Pharmaceutical Company-1 was no longer employed by Pharmaceutical Company-1 on the date this document was signed.

12. On or about January 21, 2021, FDA agents executed a search warrant at the Hexim headquarters in New Jersey. Among other things, agents found copies of certain of the fraudulent correspondence that BOUAZIZ sent to the FDA. This correspondence included the February 13, 2018 letter and the Form-356h that BOUAZIZ electronically signed under penalty of perjury and that included the following: "Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001."

13. On or about November 18, 2021, BOUAZIZ arrived in the United States. BOUAZIZ currently has a reservation for a flight to Athens, Greece, scheduled to depart on November 23, 2021 at 11:55 PM from Newark Liberty Airport in Newark, New Jersey.